PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:

Application No.:	10/530,351	**Examiner:**	HUSON, M.A.
Filing Date:	April 6, 2005	**Art Unit:**	1791
First Inventor:	Bart Gerard Boucherie	**Customer No.:**	23364
Attorney No.:	BOUC3022/JJC/PMB	**Confirm. No.:**	7774

Real Party In Interest: BOUTECH, naamloze vennootschap (Izegem, Belgium)

For: **METHOD AND DEVICE FOR MANUFACTURING PLUNGERS FOR MEDICAL SYRINGES, PLUNGERS OBTAINED THEREBY, AS WELL AS A SYRINGE FOR MEDICAL PURPOSES**

REPLY BRIEF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is a reply brief filed pursuant to the applicant's appeal to the Board of Patent Appeals and Interferences from the final rejection of claims 1 and 16 in the above identified application.

The filing of this reply brief is made within two months of the mailing of the examiner's answer and is therefore timely.

I. STATUS OF CLAIMS

A. Status of Claims in Proceeding

Claims 1 and 3-30 are currently pending in the above-identified application. Claims 1 and 3-16 are rejected and claims 17-30 are withdrawn.

B. Identification of Appealed Claims

The applicant chooses to appeal from the rejection of only independent claims 1 and 16.

Claim 2 was previously canceled.

Claims 3-15 depend from claim 1, and their patentability is based on their dependency from claim 1 and their individually recited features.

Claims 17-30 are withdrawn, and not subject to appeal.

II. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Whether claim 1 is anticipated under 35 U.S.C. § 102(b) by WIPO publication no. WO 01/70311 A1 (*Chiba*), using a translation of the related document Japanese publication no. JP 2001-259031.

Whether claim 16 is anticipated under 35 U.S.C. § 102(b) by U.S. patent no. 5,782,803 (*Jentzen*).

III. ARGUMENT

As discussed in detail below, the basis for the final rejection of claims 1 and 16 does not satisfy the requirements of anticipation of the subject matter recited in the rejected claims. Therefore, reversal of the rejection of claims 1 and 16 is respectfully requested.

A. Claim Rejections

Claim 1 was rejected under 35 U.S.C. § 102(b) as being anticipated by WIPO publication no. WO 01/70311 A1 (*Chiba*), using a translation of the related document Japanese publication no. JP 2001-259031.

Claim 16 was rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. patent no. 5,782,803 (*Jentzen*).

B. Pertinent Law

In rejecting claims under 35 U.S.C. § 102(b), anticipation can only be established when a single prior art reference discloses, either expressly or under the principles of inherency, each and every element of the claimed invention. *See for example, In re Paulsen*, 30 F.3d 1475, 1480-1481, 31 USPQ2d 1671, 1675 (Fed. Cir. 1994): and *In re Spada*, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990). The same invention must be shown in as complete detail as is described in the claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). It is recognized that the elements must be arranged as required by the claim, however, there is no *ipsissimis verbis* test (identity of terminology is not required). *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990).

The dispositive question regarding anticipation is whether one skilled in the art would reasonably understand or infer from the prior art reference's teachings that every claim limitation was described in that single reference. *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1368, 66 USPQ2d 1801, 1809 (Fed. Cir. 2003). To establish anticipation, it must be shown that a single prior art reference describes each and every limitation of a claimed invention. *Hybritech Inc. v.*

Monoclonal Antibodies, Inc., 802 F.2d 1367, 1379, 231 USPQ 81, 90 (Fed. Cir. 1986; cert. denied, 480 U.S. 947 (1987). The description in the reference may be either express or inherent. *Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

C. The subject matter recited in claim 1 is not anticipated by the *Chiba* publication

The arguments presented in sections VII(C)(1)-(2) of the appeal brief filed July 14, 2008 are incorporated in their entirety herein by reference.

1. Response to item (10) (Response to Argument (Claim 1-Heading (C)))

The examiner's answer refers to Fig. 1 of the *Chiba* publication as showing a gasket 6 (equated to the piston recited in claim 1) that is free of any flash lines and/or gate points for the plastic.

Turning to Figs. 2(a)-2(c) of the *Chiba* publication it is seen that there are indeed both flash lines, formed on the gasket 6 at the intersection of the mold parts 21a and 21b, and a gate point for the plastic, "pin point gate 23 located in the surface center section of the gasket 6" (*Chiba* publication paragraph [0015]).

At least the formation of the gate point for the plastic is acknowledged on page 5 of the examiner's answer. The gate point is formed via the injection of plastic through pin point gate 23 in the mold between mold parts 21a and 21b. A runner section 25 connects the pin point gate 23 with the injection molding machine 24, and allows material 26 to form therein during formation of the gasket. Even when the extra material is removed during final processing, there will remain a visible gate point for the plastic in the center section of the gasket 6.

While the flash lines and the gate point for the plastic may not actually appear to be shown in Fig. 1, this may be for a number of reasons that do not involve the steps according to the method as recited in claim 1.

In particular, since the drawing of Fig. 1 is shown as a cross-sectional view, if the view is taken along any plane other than the plane that contains the flash lines, the flash lines would not appear in the drawing of Fig. 1.

Alternatively, even if the cross-sectional view is taken along the plane that contains the flash lines, since there is a necessary compression of the gasket 6 at the interface between the gasket 6 and the walls 4a of the outer case 4 to ensure sealing therebetween, such flash lines would also be compressed, and not necessarily visible in the drawing of Fig. 1.

Therefore, in view of Figs. 2(a)-2(c), which show that flash lines will be formed between the molds 21a and 21b, and the indeterminate nature of the drawing of Fig. 1, and further since no discussion appears in the *Chiba* publication of removing the flash lines, it cannot be said that the gasket 6 is formed free of flash lines, as is required by the method recited in pending claim 1.

Further still, even though a gate point for the plastic may not appear to be shown in Fig. 1, in view of Figs. 2(a)-2(c), which show a pin point gate 23, and since even when the excess material formed in the runner section 25 is removed from the gasket 6, a visible gate point for the plastic will remain in the center section of the gasket 6, it cannot be said that the gasket 6 is formed free of a gate point for the plastic, as is required by the method recited in pending claim 1.

The examiner's answer attempts to explain the apparent absence of the flash lines or the gate point for the plastic in the gasket 6 of the *Chiba* publication by suggesting that a finishing step is performed to remove the flash lines or the gate point for the plastic in the gasket 6.

There is simply no discussion in the *Chiba* publication of such a finishing step. Accordingly, it cannot be said that the *Chiba* publication discloses a gasket 6 that is formed free of flash lines and/or gate points for the plastic, as is required by pending claim 1.

Further, such finishing steps as suggested in the examiner's answer, without any evidentiary basis, would not likely be successfully used to modify the gasket 6 of the *Chiba* publication.

In particular, while it may be possible that one could polish or cut away an extrusion remnant (flash line), such a procedure may not be able to remove the entire remnant, may leave debris behind, or may damage the surfaces of the gasket. In particular, removal of the flash lines from the sealing surface of the gasket 6 of the *Chiba* publication would be likely to have an adverse effect on the diameter and roundness of the gasket 6, and thus would be likely to have an adverse effect on the sealing at the interface between the gasket 6 and the walls 4a of the outer case 4.

In any event, the *Chiba* publication is silent about whether such finishing steps are actually performed.

Even if such finishing steps are performed, the *Chiba* publication would still not disclose the method recited in claim 1, which requires, *inter alia*, that the piston body is formed by injection molding and having a front side and a side wall being formed such that the front wall and side wall thereof are free of any flash lines and/or gate points for the plastic.

In other words, the front wall and side wall of the piston body are formed free of any flash lines and/or gate points for the plastic at the injection molding step, and not by a finishing step as suggested in the examiner's answer at page 5.

While the examiner's answer is correct in that pending claim 1 does not preclude any finishing steps, such a finishing step to remove any flash lines and/or gate points for the plastic is unnecessary in the method of pending claim 1, which requires that the front wall and side wall of the piston body are formed free of any flash lines and/or gate points for the plastic at the injection molding step.

Therefore, in view of the above discussion, it is apparent that the *Chiba* publication fails to disclose or suggest forming a piston body from plastic having a

front side and a side wall that are free of any flash lines and/or gate points for the plastic at the injection molding step, as is required by pending claim 1.

D. The subject matter recited in claim 16 is not anticipated by the *Jentzen* patent

The arguments presented in sections VII(D)(1)-(2) of the appeal brief filed July 14, 2008 are incorporated in their entirety herein by reference.

1. Response to item (10) (Response to Argument (Claim 16-Heading (D)))

The examiner's answer reiterates the use of the embodiment of Fig. 7 of the *Jentzen* patent to show the method recited in pending claim 16.

As acknowledged on page 6 of the examiner's answer, the sealing means 300 of the *Jentzen* patent is a separate element from the plunger end 202 of the *Jentzen* patent.

The examiner's answer relies on the cross-hatching shown in Fig. 7 for the two elements, and the discussion in column 3, lines 42-51 to show that two different materials are utilized to form the sealing means 300 and the plunger end 202.

Even if the sealing means 300 and the plunger end 202 are formed of two different materials, and the plunger end 202 is considered a part of the piston body that protrudes from the piston body, as is required by pending claim 16, the *Jentzen* patent still fails to disclose the materials forming the piston body and the protruding part are injected against one another such that the piston body is made in one piece with a plunger body, as is also required by pending claim 16.

The embodiment of Fig. 7 of the *Jentzen* patent clearly describes a distinct sealing means 300 that "rides in a recess on the plunger" (col. 5, lines 14-16). This sealing means 300, therefore, cannot be considered to be "made in one piece with a plunger body" as is required by pending claim 16.

Further, while the *Jentzen* patent may disclose injection molding the sealing element 300 in column 3, lines 44-45, which is not explicitly set forth in this passage, and injection molding of the plunger end 202 in column 3, lines 46-50, there is no discussion that the sealing element 300 and the plunger end 202 are injected against one another such that the piston body is formed in one piece with a plunger body, as is required by pending claim 16.

The examiner's answer indicates, without any evidentiary support, that the sealing element 300 and the plunger end 202 are injected against one another to form a single piece.

This assertion is unsupported, and factually baseless, since the *Jentzen* patent clearly discloses that the sealing means 300 is a distinct element that "rides in a recess on the plunger" (col. 5, lines 14-16).

While the *Jentzen* patent is actually silent as to how the sealing means 300 is applied to the recess, a typical manner of applying elastomeric donut, such as sealing means 300, in a recess is to expand the elastomeric donut and place the donut within the recess. The expansion is then released so that the donut will contract and sit within the recess. There is nothing in the *Jentzen* patent to suggest that the sealing means 300 is applied to the recess in any other manner.

Therefore, in view of the above discussion, it is apparent that the *Jentzen* patent fails to disclose or suggest the materials forming the piston body and the protruding part are injected against one another such that the piston body is made in one piece with a plunger body.

IV. Conclusion

For the reasons set forth above, independent claims 1 and 16 of the pending application define subject matter that is not anticipated within the meaning of 35 U.S.C. § 102(b) by either the *Chiba* publication, or the *Jentzen* patent, respectively.

Reversal of the rejections of claims 1 and 16 are respectfully requested. Since the remaining pending claims 3-15 depend from claim 1, the reversal of the rejections of these claims is likewise requested.

The Fee required by 37 C.F.R. § 1.17(c) has been previously submitted. The Office is authorized to charge any additional fees associated with this communication to Deposit Account No. 02-0200.

BACON & THOMAS, PLLC
625 Slaters Lane, Fourth Floor
Alexandria, Virginia 22314-1176
Phone: (703) 683-0500
Facsimile: (703) 683-1080

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Respectfully submitted,

/Patrick M. Buechner, Reg. #57,504/

PATRICK M. BUECHNER
Attorney for Applicants
Registration No. 57,504